

REMARKS

Claims 1-6 are pending. Examiner's objections and rejections will be addressed below.

Rejection Under § 101

Claims 1 and 6 were amended to reflect that the polynucleotide and polypeptide are "isolated."

Clarification is requested as to Examiner's assertion that claim 4 should be amended. Both claims 3 and 4 are directed in part, to a vector containing the isolated polynucleotide. Thus, any vector having this isolated polynucleotide would necessarily comprise statutory subject matter.

Withdrawal of the rejection is respectfully requested.

Sequence Rules

The specification has been amended to include the proper sequence identifier after each oligo disclosed on pages 37-40.

During the preparation of this amendment, an error in the sequence listing was found. Specifically, SEQ ID NO: 45 as disclosed on page 39 included an extra nucleotide ("c") at the 3' end. As a result, an amended sequence listing has been submitted separately from this amendment.

No amendment to the specification added new matter in view of the fact that the disclosure of the complete sequence of SEQ ID NO: 45 was included in the specification as originally filed.

§§ 112 and 102(b)

A. The rejections under these provisions are largely based on the "70% identity" limitation in claim 6. These rejections are rendered moot by the corresponding deletion of this limitation in the foregoing amendment.

Withdrawal of this basis of rejection is respectfully requested.

B. Examiner rejected claim 4-5 for reading on *in vivo* transfection, which he asserts is not enabled by the specification. Applicants respectfully disagree that the claims read on *in vivo* transfected cells. Further, Examiner's statements effectively requires that Applicants convert these claims to product by process claims. In other words, Examiner is requiring that Applicants recite "a cell comprising the vector of claim 3, wherein the cell is transfected *in vitro*."

If Examiner could suggest some amendments that are not as narrow as this, it would be appreciated if he contacted the undersigned to discuss them.

A lesser amendment to claim 4, e.g., adding a limitation merely requiring that the *host cell is a cultured host cell* is meaningless even with the term "cultured host cell." For example, a cell obtained from a transgenic animal and placed in culture would be encompassed by such a claim, although the cell was actually prepared by *in vivo* gene transfer procedures. Therefore, merely adding terms such as culturing will not serve Examiner's goal to restrict the host cell to the scope of the claims that he deems proper.

Further, there are other interpretations that persons in the art would understand to be encompassed by these claims. For example, if freshly isolated cells were obtained

from a subject and transfected *in vitro*, those cells may be reintroduced into a living subject. Subsequent to these cells multiplying, these cells would be clearly encompassed by a cell having the vector of claim 3. Thus, a limitation requiring the cells to be transfected *in vitro* is overly narrow in view of the state of knowledge in the art.

Last, there seem to be many patents issuing that do not require that a claim limitation directed to a host cell be further limited *as being created by in vitro transfection*. In fact, the undersigned cannot readily recall such a claim.

Limitations that actually encompass *in vivo* gene transfer, like claims to any *in vivo* treatment or therapy, requires *in vivo* experimental data. In view of the fact that the instantly claimed host cell does not have any *in vivo*-oriented language, it is highly unlikely that the a host cell prepared by *in vivo* transfection would, in reality, read on or infringe an *in vitro* transfected cell.

It is respectfully requested that this rejection of claims 4-5 be withdrawn.

CONDITIONAL PETITION FOR EXTENSION OF TIME

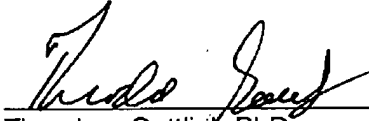
If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

ADDITIONAL FEES

Please charge any further insufficiency of fees, or credit any excess to Deposit Account No. 14-1263.

Respectfully Submitted,

Norris, McLaughlin & Marcus
220 East 42 nd Street
New York, NY 10017
Telephone (212) 808-0700
Facsimile (212) 808-0844


Theodore Gottlieb, PhD
Reg. No. 42, 597

Certificate of Transmission

I hereby certify that this correspondence is being transmitted by facsimile to the U.S. Patent and Trademark Office (Fax No. (703)872-9306

on September 15, 2004.
(Date)

THEODORE GOTTLIEB

Typed or printed name of transmittor

Signature

